EXHIBIT FF

MICHAEL R. REED

UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

- -

In re Bair Hugger Forced
Air Warming Products
Liability Litigation,

MDL No. 14-2666 (JNE/FLN)

- -

- -

VIDEOTAPED DEPOSITION OF

MICHAEL R. REED

- -

London, United Kingdom

Taken December 4th, 2016 By Rose Kay

Job No. 115951

APPEARANCES:

THE EXAMINER
Allen Dyer

SERJEANTS' INN CHAMBERS
85 Fleet Street
London EC4Y 1AE, United Kingdom
By: Jonathan Holl-Allen, Esq.
For the witness

- and -
MDU SERVICES LIMITED
One Canada Square
London E14 5GS, United Kingdom
By: Ediri Okonedo, Esq.
For the witness

BLACKWELL BURKE
431 South Seventh Street
Minneapolis, Minnesota 55415
By: Corey Gordon, Esq.
For 3M Company and Arizant Healthcare, Inc.

APPEARANCES (CONT'D):

KENNEDY HODGES
4409 Montrose Blvd.
Houston, Texas 77006
By: Gabriel Assaad, Esq.
For Plaintiffs

- and -
MESHBESHER & SPENCE
1616 Park Avenue
Minneapolis, Minnesota 55404
By: Genevieve Zimmerman, Esq.
For Plaintiffs

Also Present: Gerlando Scaffidi, videographer

I N D E X

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conductive fabric was made in all pre-selected orthopaedic theaters starting on 1st March, 2010, and ending on 1st June, 2010.
A. Yes.
Q. So that the transition period would be March, April, May of 2010; correct?
A. Yes.
Q. So that would be three months?
A. Yes, that looks right.
THE EXAMINER: So prior to March 1st, 2010 it was Bair Hugger. And after 1st June, it was Hot Dog.
A. Yes.
THE EXAMINER: Thank you.
BY MR. GORDON:
Q. So the Bair Hugger only period was July --
A. July 2008.
Q. July 2008 to the end of February 2010?
A. Yes.
Q. And --
A. Yes.
Q. And after those three months, there was use of both Hot Dog and Bair Hugger.
A. (Nods.)
Q. Is that right? You have to say "yes" or "no".

A. Oh sorry, yes.
Q. That is all right. And the last seven months of the period you looked at, it was Hot Dog only; is that right?
A. So is it seven months or six?
Q. June, July, August, September, October, November, December.
MR. HOLL-ALLEN: Seven.
A. Seven. There you go.
BY MR. GORDON:
Q. So the Bair Hugger only period was 20 months; is that right?
A. Well, it was that time, certainly. That feels right.
THE EXAMINER: 20 months.
BY MR. GORDON:
Q. How -- were the data that you looked at collected at more than one hospital?
A. No.
Q. Which hospital were these data from?
A. Wansbeck Hospital.
Q. Do you recall how you initially gathered the data for analysis?
A. So the data is gathered by a team of nurses, surveillance nurses. That's their job. That's what

they do. That's all they do.
Q. I was being a little bit more ministerial in my question. If you go to the file cabinet and pull it out, is it computerized data, is it ...?
A. Ah, so I asked them to -- I mean, the way this works is that we have a report which is produced, of which there's some in here actually, which is all the various operations that are done, the risk factors those patients have and then the outcomes they have; which is generated by the hospital systems.
But infection is a difficult one. You can't rely on computers to sort of diagnose that, or you can't rely on coding. So it's a specific -- you need a specific team. So they have got that and then they have added their call on whether there is an infection or not, to that.
Q. Let me ask you to take a look in volume 3, at pages 788 through 1081.
(Exhibit Reed 3 marked for identification.)
MR. ASSAAD: 7 ...?
BY MR. GORDON:
Q. 788 through 1081.
Does that look familiar to you?
A. Yes.
Q. Is that the form of the data on infections that you

would have pulled and provided to your co-authors?
A. Yes.
Q. Who did the actual data analysis?
A. For this paper, Mark Albrecht.
Q. So were these data, pages 788 through 1081, provided by you to Mr. Albrecht?
MR. ASSAAD: Objection, lack of foundation.
THE EXAMINER: You may answer.
A. I expect so. I don't remember that, but I imagine I did. There was nothing on here that would -- you know, there is no data governance issues with this. So I think, I am almost certain I would have provided it.
THE EXAMINER: Well, it starts on 1st October, 2007, according to page 788.
A. Yes. I mean, he wouldn't have analyzed that; but this data goes back, in fact, to 2002.
MR. ASSAAD: I would just like a clarification for my objection. I am uncertain whether or not this witness is saying that this is exactly what he gave or used, or whether he says it looks like it, but he is not clear. I just want a clarification.
THE EXAMINER: Which is it, Mr. Reed?
A. In all honesty, it looks like it. I don't know if it is what I gave. But I don't know where he would have got

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A. No. We have always done that, but I think you are alluding to sensitive staph aureus.
Q. That was my next question. So you have always done the first screening?
A. Yes, I can't remember when we didn't.
Q. But my next question -- yes. So did there come a time when you -- was there a time when you had not been screening for methicillin susceptible staphylococcus aureus, and you started screening for that?
A. So that was in early 2010, I think we started screening for that.
Q. And was it just screening, or did somebody who had -- did you take some action?
A. So we would decolonize patients to -- essentially what you are trying to do is to reduce the load of this particular bug in someone's nose or on their hands or whatever.
Q. So some of the Bair Hugger only patients would have not had the benefit of MSSA screening; some of them would have? Either way -- did you say February 2010?
A. I think it was January, but ...
Q. Okay. So at the very end of the Bair Hugger only period?
A. Yes.

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Q. So if you were the Bair Hugger -- some of the Bair Hugger patients at the very end would have had MRSA screening and all of the Hot Dog only patients had the benefit of MSSA screening?
A. That is due. But what I would say is that there is no evidence that it reduces infection rates in this group; certainly at this point. That may not be the case now, six years down the line. But yes, it was introduced with that intention.
Q. Did there come a point in time when you instituted pre-warming of patients for hip and knee ...?
A. Yes.
Q. When was that?
A. It will probably be on the timeline.
THE EXAMINER: What does it mean?
A. So essentially, if you warm someone up before their operation, then they are less likely to get cold during their operation. If you are less likely to get cold during the operation, then it reduces your complications of bleeding, heart attacks and perhaps infection.
BY MR. GORDON:
Q. Well, had you seen any studies before you implemented the pre-warming, to address that specific issue; does it have any impact on infection?

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A. So it does have an impact on infection. But I think what's less certain is whether it has an impact on infection if you warm them in theater as well. So isolated pre-warming has an impact on infection.
In fact, David Leaper, who you are going to meet, published that in a very good large study. But my recollection is that those patients weren't warmed during surgery.
Q. Are you talking about the Melling paper from 2001?
A. Yes.
Q. Was there a study closer in time, so when you switched to pre-warming that you had seen ...?
A. So I have certainly seen a study that shows that if you pre-warm people, they are less likely to get cold, so that's like a proxy. So I have certainly had that in some of my presentations.
Q. Have you ever indicated that in your presentations, that you read the New England Journal and found some article about a significant reduction in infection rates by adding pre-warming, and then you decided to do that as part of your routine procedures?
MR. ASSAAD: Objection, leading.
A. That was David Leaper; David Leaper's study, I think. I think that was in the Lancet, actually, David Leaper's

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study. Is pre-warming in the New England Journal of Medicine? I am not aware of that.
BY MR. GORDON:
Q. Okay. I am not going to take time going into too many more ...
A. There is now good evidence evolving, but it is coming into practice as a definite now, compulsory. This is six years down the line.
Q. When did you start pre-warming patients?
A. It is probably on the timeline. Can you point that out for me?
Q. I think it is probably the second quarter of 2010.
A. Okay. It is likely to be correct if it is on here.
THE EXAMINER: Yes, it is part of the entry in the yellow box.
BY MR. GORDON:
Q. The yellow box up on the top bit.
A. Yes, I am not sure that the Lancet study -- and I am genuinely not sure. But I think that is not based on the people who are warmed during the operation as well. I think in David's study, they were only pre-warmed.
Q. The 2001 Melling --
A. Yes.
THE EXAMINER: So in your hospital, as from June 2010 they

were both pre-warmed and warmed during the operation?
A. Yes, yes. And the major benefit of that would be reducing bleeding, reducing anxiety, reducing pain perhaps as well, reducing transfusion rates. It has a lot of advantages. It does not relate specifically to infection and I am not sure that warming and pre-warming together reduce infection rates. Either is probably fine.
BY MR. GORDON:
Q. Now, at some point you switched to chlorhexidine as a skin prep; is that right?
A. (Nods.)
Q. When was that?
A. In my recollection, late 2010, right at the end of the -- I will save you some time. Right at the end of the -- actually, I can't remember which period it was.
THE EXAMINER: Look at the little red box for Q4/2010.
A. Okay, there you go, right. At the end of 2010. So -- yes.
BY MR. GORDON:
Q. Did there come a point in time when you instituted a root cause analysis of infections?
A. Yes. I think that was pretty early on, actually.
Q. Like the first quarter of 2009?

A. Yes, or even before that, I suspect, actually.
THE EXAMINER: It says "underway", which is not exactly very precise.
BY MR. GORDON:
Q. I just want to cut to the chase. Would you agree that there were -- that there was, first of all, a serious problem with infections in the knee and joint area, in the late 2008/early 2009 timeframe?
MR. ASSAAD: Objection to form, argumentative.
THE EXAMINER: You may answer.
A. So I mean, I would definitely agree, we were trying to reduce our infection rates. And it's a devastating complication and we were trying to reduce them. And you know, I think as we have made very, very clear publicly, we have tried lots of things to reduce it.
BY MR. GORDON:
Q. And over a period of time, you implemented a whole variety of infection control procedures?
A. Yes.
Q. And it wasn't just switching from Hot Dog -- or from Bair Hugger to Hot Dog; right?
A. So in the time period that we have put in the paper, I don't think there's anything significant that we haven't mentioned in the paper, which is the gentamicin

and the rivaroxaban, in terms of -- in terms of affecting infection rates.
You know, there are other things like MSSA screening which was introduced.
But at the time of this paper and still, there is no evidence to say that it reduces infection rates, staph aureus infection rates in joint replacement patients. Now, we are doing a piece of work now that does actually, I think, show that. But that is not in the literature at all, even six years down the line.
Q. Just looking at the timeline and the picture of you standing in front of that thing, the graph that starts out very high and goes down very quickly. Was that reflective of what was happening to the SSI rates?
A. So I mean, this chart is the SSI rates, but it is not -- you need to understand, it is not the Wansbeck primary joint replacement infection rates. This is --
Q. The whole system?
A. -- the conglomerate of superficial and deep revision, hip fracture patients, hemiarthroplasties, DHSs, and it is a large group. And the value of that is that you can make a change and hopefully track the advantage of that.
Q. There came a point in time when you stopped using one particular operating theater; correct?

A. Yes.
Q. Why was that?
A. That was, I think here.
Q. I think it was a little later in time.
A. The laminar flow repaired in Wansbeck. Is that the one you ...
Q. And that was when? That was -- it is kind of hard to tell from the timeline, other than that it was --
A. That was quarter 3/2008. Quarter -- at the start of quarter 3.
Q. Now, I --
A. To June 2008.
Q. From memory, I think it is in the orange box on the far right.
A. Okay.
Q. After the --
THE EXAMINER: That is Q4 of 2013, theater 2, WGH, closed to all TKH joint replacements.
A. Yes, so there was a brief period. That is not actually my theater, but there was a brief period that it was closed.
BY MR. GORDON:
Q. Okay. It was not a permanent closure? I don't want to talk about that, then.